

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
NORTHERN DIVISION

_____)	
UNITED STATES OF AMERICA)	
and STATE OF MISSOURI,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No.
)	
TEVA PHARMACEUTICALS USA, INC.)	
)	
Defendant.)	
_____)	

COMPLAINT

The United States of America, acting at the request of the administrator of the United States Environmental Protection Agency (“EPA”), and the State of Missouri, at the relation of Attorney General Chris Koster and the Missouri Department of Natural Resources (“MDNR”), file the complaint and allege as follows:

NATURE OF THE ACTION

1. This is a civil action brought pursuant to the Clean Air Act, 42 U.S.C. § 7413 et seq.; the Missouri Air Conservation Law, Mo. Rev. Stat. § 643.010 et seq.; the Clean Water Act, 33 U.S.C. § 1319 et seq.; the Missouri Clean Water Law, Mo. Rev. Stat. § 644.006 et seq.; the Resource Conservation and Recovery Act, 42 U.S.C. § 6901 et seq.; and the Missouri Hazardous Waste Management Law, Mo. Rev. Stat. § 260.003 et seq.; to obtain civil penalties and injunctive relief against Teva Pharmaceuticals USA, Inc., for violations of the regulations and requirements applicable to the handling of hazardous air pollutants, hazardous waste and the

discharge of pollutants to a city-owned wastewater treatment plant. The violations alleged in the complaint occurred at a chemical manufacturing facility located in Mexico, Missouri.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, 1355 and 1367, 33 U.S.C. § 1319(b), 42 U.S.C. § 7413(b), 42 U.S.C. § 6928, and Mo. Rev. Stat. §§ 260.425.1, 643.151.3, and 644.076.1.

3. Venue is proper in the Eastern District of Missouri pursuant to 33 U.S.C. § 1319(b), 42 U.S.C. § 7413(b), 28 U.S.C. §§ 1391 and 1395, 42 U.S.C. § 6928(a), and Mo. Rev. Stat. §§ 260.425.1, 643.151.3, and 644.076.1, because Teva Pharmaceuticals USA, Inc. is found in and conducts business in this District and because the alleged violations occurred within this District.

NOTICE

4. The United States has notified the State of Missouri of the commencement of this action as required by 42 U.S.C. § 7314(b).

DEFENDANT

5. Teva Pharmaceuticals USA, Inc. (“Teva”) is incorporated in Delaware and is an active corporation registered to do business in Missouri.

6. Teva is a wholly owned subsidiary of Teva Pharmaceuticals Industries, Ltd., which is headquartered in Israel.

7. Teva is a person as that term is defined in the Clean Water Act, 33 U.S.C. § 1362(5), the Clean Air Act, 42 U.S.C. § 7602(e), the Resource Recovery and Conservation Act, 42 U.S.C. § 1004(15), the Missouri Hazardous Waste Management Law, Mo. Rev. Stat. §

260.360(17), the Missouri Air Conservation Law, Mo. Rev. Stat. § 643.020(37), and the Missouri Clean Water Law, Mo. Rev. Stat. § 644.016(14).

8. Teva is the owner and operator of a chemical manufacturing facility in Mexico, Missouri (“Teva’s Mexico Facility”). *See* 42 U.S.C. § 7412(a)(9).

9. Teva is the “owner” and “operator” of Teva’s Mexico Facility, as those terms are defined in 40 C.F.R. § 260.10, as incorporated by reference at Mo. Code Regs. 10, 2-3.260(1).

10. Teva’s operations at the Mexico, Missouri facility fall within SIC codes 2833 and 2834 and NAICS codes 325411 and 325412.

GENERAL ALLEGATIONS

A. The Facility

11. At Teva’s Mexico Facility, Teva produces antibiotics and intermediates using approximately six pharmaceutical manufacturing process units and operates a wastewater treatment plant.

12. Because Teva’s Mexico Facility uses and emits hazardous air pollutants, discharges pollutants to the City of Mexico’s POTW, and generates hazardous waste, Teva is subject to requirements of the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, the Missouri Air Conservation Law, the Missouri Clean Water Law, and the Missouri Hazardous Waste Management Law.

B. The Clean Air Act and the Missouri Air Conservation Law

13. The Clean Air Act establishes a regulatory framework designed to protect and enhance the quality of the nation's air so as to promote the public health and welfare and the productive capacity of its population. 42 U.S.C. § 7401.

14. The Clean Air Act requires EPA to promulgate regulations that establish national emission standards for each category of major sources of listed hazardous air pollutants.

42 U.S.C. § 7412(d).

15. Prior to establishing the emissions standards for a particular industry, EPA determines the emissions levels already achieved by the best-performing similar facilities, referred to as the Maximum Achievable Control Technology (“MACT”). The national emissions standards for hazardous air pollutants (“NESHAPs”) then require each source within the category to install that MACT.

16. For the pharmaceutical industry, EPA promulgated the NESHAPs pursuant to 42 U.S.C. § 7412 at 40 C.F.R. Part 63, Subpart GGG (“Subpart GGG”). Subpart GGG establishes specific standards, test methods and initial compliance requirements for four source categories: Process Vents, Storage Tanks, Equipment Leaks, and Wastewater. *See* 40 C.F.R. Part 63, Subpart GGG. Additionally, specific monitoring, reporting, and record keeping requirements are associated with the control equipment options selected to comply with the standards. The Missouri Air Conservation Law incorporates Subpart GGG as a rule, which is enforced by the Missouri Department of Natural Resources. Mo. Code Regs. tit. 10, 10-6.075.

17. Each owner or operator subject to the Subpart GGG is required to select the specific control equipment that will be used to comply with the standard, and to list all of the rule requirements that apply to any specific compliance option. *See* 40 C.F.R. §§ 63.1252 to 63.1256.

18. Subpart GGG also imposes Equipment Leak Standards, found in 40 C.F.R. § 1255, known as LDAR (leak detection and repair) requirements. LDAR requirements generally include identification and monitoring of equipment, repair of leaks, recordkeeping and reporting

to ensure that any leaks of air pollutants from equipment used in the manufacturing of organic chemical products are timely detected and repaired.

19. As set forth in 40 C.F.R. § 63.1255, the LDAR requirements apply to, *inter alia*, pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, and connectors that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year within a source subject to the provisions of a specific subpart in 40 C.F.R. Part 63 that references Subpart GGG.

20. The term “in organic hazardous air pollutant service” means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic hazardous air pollutants. 40 C.F.R. § 63.1251.

C. The Clean Water Act and the Missouri Clean Water Law

21. The objective of the Clean Water Act is to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.” 33 U.S.C. § 1251(a).

22. The Clean Water Act, 33 U.S.C. § 1311(a) prohibits the discharge of pollutants into navigable waters of the United States by any person, except as in compliance with other sections of the Clean Water Act, including 33 U.S.C. §§ 1317 and 1342.

23. The Administrator of the EPA may issue NPDES permits that authorize the discharge of pollutants into navigable waters of the United States, subject to conditions and limitations set forth in such permits. 33 U.S.C. § 1342(a).

24. Effluent limitations are among the conditions and limitations prescribed in NPDES permits issued under 33 U.S.C. § 1342.

25. A state may establish its own NPDES permit program and, after receiving approval of its program from the Administrator of the EPA, may issue Clean Water Act NPDES permits. 33 U.S.C. § 1342(b).

26. Pursuant to 33 U.S.C. § 1317, EPA has established standards that govern discharges into publicly owned treatment works (“POTWs”) that discharge to navigable waters. The General Pretreatment Regulations, found at 40 C.F.R. Part 403, are designed to ensure that each POTW can comply with its NPDES permits.

27. Among other things, the General Pretreatment Regulations prohibit an “industrial user” from causing “interference” with the operation of a POTW and “pass through” of pollutants at a POTW. 40 C.F.R. §§ 403.5(a)(1), (b)(4).

28. An “industrial user” is a source that discharges pollutants to a POTW from a non-domestic source. 40 C.F.R. § 403.3.

29. “Interference means a Discharge which alone or in conjunction with a discharge or discharges from other sources, both: (1) Inhibits or disrupts the POTW, its treatment processes or operations, or its sludge processes, use or disposal; and (2) Therefore is a cause of a violation of any requirement of the POTW’s NPDES permit (including an increase in the magnitude or duration of a violation)” 40 C.F.R. § 403.3.

30. “Pass Through means a Discharge [from an Industrial User] which exits the POTW into waters of the United States in quantities or concentrations which, alone or in conjunction with a discharge or discharges from other sources, is a cause of a violation of any requirement of the POTW’s NPDES permit (including an increase in the magnitude or duration of a violation).” 40 C.F.R. § 403.3.

31. The General Pretreatment Regulations also provide for the development of local limits developed to protect a POTW from the introduction of pollutants from an industrial user into the POTW – including pollutants that may cause interference or pass through. *See* 33 U.S.C. § 1317(d); 40 C.F.R. § 403.5(d).

32. In addition, EPA has promulgated pretreatment standards for specified categories of industrial users pursuant to Section 307(b) of the CWA. These categories of industrial users, or “categorical” industrial users, are subject to specific pretreatment requirements set forth at 40 C.F.R. Parts 405-471.

33. The pharmaceutical manufacturing industry is one of the categories of industry subject to categorical treatment standards. *See* 40 C.F.R. Part 439. These categorical treatment standards apply to process wastewater discharges resulting from the research and manufacture of pharmaceutical products that reported under SIC code 2833, 2834 and 2836. The Categorical Pharmaceutical Pretreatment Standards impose effluent limits that are concentration-based (or alternative production-based), and include daily maximums and monthly averages.

34. Noncompliance with any pretreatment standard, prohibition or effluent standards is a violation of the Clean Water Act and the Missouri Clean Water Law. 33 U.S.C. § 1317; Mo. Rev. Stat. §§ 644.051.1(3) and 644.076.1, and Mo. Code Regs. tit. 10, 20-6.100(4)(B)4 and (D).

35. A state may establish its own pretreatment program by receiving approval of its program from the Administrator of EPA. 33 U.S.C. § 1342(b).

36. The Missouri Department of Natural Resources (“MDNR”) is the state agency with the authority to administer the federal NPDES program in Missouri pursuant to 33 U.S.C. § 1342, implementing regulations, and a Memorandum of Understanding dated October 30, 1974.

MDNR is also the state agency with the authority to administer the Pretreatment Program in Missouri pursuant to 33 U.S.C. § 1342, implementing regulations, and a Memorandum of Understanding dated June 3, 1981. As such, MDNR is the Approval Authority as defined by 40 C.F.R. § 403.3(c).

37. The pretreatment program of the City of Mexico, Missouri, was approved by MDNR on May 9, 1990, and therefore the City of Mexico, Missouri (hereinafter “City of Mexico” or “City”) is the Control Authority as defined by 40 C.F.R. § 403.12(a).

D. The Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law

38. Federal regulation of hazardous waste is primarily based on the Resource Conservation and Recovery Act, enacted on October 21, 1976 to amend the Solid Waste Disposal Act, and on the Hazardous and Solid Waste Amendments, enacted by Congress in 1984 to further amend the Solid Waste Disposal Act. The Resource Conservation and Recovery Act establishes a “cradle-to-grave” program to be administered by the Administrator of EPA for regulating the generation, transportation, treatment, storage, and disposal of hazardous waste. 42 U.S.C. § 6901 et seq.

39. Pursuant to its authority under the Resource Conservation and Recovery Act, EPA has promulgated regulations at 40 C.F.R. Parts 260 through 272 applicable to hazardous waste generators, transporters and treatment, storage and disposal facilities. These regulations provide detailed requirements to govern the activities of those who generate hazardous waste and those who are lawfully permitted to store, treat and dispose of hazardous waste. They generally prohibit treatment, storage and disposal of hazardous waste without a treatment, storage, or disposal (TSD) permit or equivalent “interim status.” 42 U.S.C. § 6925.

40. Pursuant to Section 3006 of the Resource Conservation and Recovery Act, 42 U.S.C. § 6926, and 40 C.F.R. Part 271, EPA may authorize a state to administer a state hazardous waste program in lieu of the federal program when it deems the state program to be equivalent to the federal program.

41. EPA granted final authorization to the State of Missouri to administer its hazardous waste program in lieu of the federal program on November 20, 1985, 50 F.R. 4770, and has approved subsequent revisions to the program. MDNR is the State agency designated to maintain the authorized Resource Conservation and Recovery Act program in Missouri. Missouri has promulgated regulations that incorporate by reference EPA's Resource Conservation and Recovery Act regulations and impose additional requirements. Mo. Code Regs. tit. 10, 25-3.260, 25-4.261, 25-5.262, 25-6.263, 25-7.264 through 25.270, and 25-11.279.

42. Specifically, the federal hazardous waste program is managed in the State of Missouri pursuant to the Missouri Hazardous Waste Management Law, Mo. Rev. Stat. §§ 260.350 through 260.434, and the regulations promulgated thereunder.

43. EPA's and Missouri's laws and regulations (as relevant to this lawsuit) require that all generators of hazardous waste must:

- a. determine whether generated solid wastes are hazardous, 40 C.F.R. § 262.11, incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);
- b. not accumulate hazardous waste on-site at all, except that it may do so for no more than ninety days (for a Large Quantity Generator) if it adheres to strict regulatory requirements, 40 C.F.R. § 262.34(a), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1). Any generator that either fails to comply with these requirements or exceeds the 90-day accumulation period

- is considered to be an operator of a storage facility and must obtain either (1) a Resource Conservation and Recovery Act permit or (2) interim status. 42 U.S.C. § 6925, Mo. Rev. Stat. § 260.390, and 40 C.F.R. § 262.34(b), incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);
- c. store, transport, and dispose of hazardous waste only in compliance with a permit or interim status, 42 U.S.C. § 6925, Mo. Rev. Stat. § 260.390;
 - d. store incompatible materials in the same tank system such that the mixture or commingling of incompatible wastes does not generate extreme heat or pressure, fire or explosion, or violent reaction, 40 C.F.R. § 265.199(a), referencing 40 C.F.R. § 265.17(b), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);
 - e. obtain a written assessment reviewed and certified by a qualified Professional Engineer attesting that a tank system has sufficient structural integrity and is acceptable for storing and treating hazardous waste, prior to placement of hazardous waste into the tank system, 40 C.F.R. § 265.192(a), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);
 - f. utilize containment systems for tanks with impervious coatings that are free from gaps or cracks, Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.E. referencing Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.D.(III)(a);
 - g. utilize secondary containment systems for tanks that are designed, installed, and operated to prevent any migration of wastes or accumulated liquid out of the system and equipped with a liner that is free of cracks or gaps, 40 C.F.R.

§ 262.34(a)(1)(ii) referencing 40 C.F.R. § 265.193, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);

- h. provide secondary containment systems with a leak detection system that is designed and operated so that it will detect the failure of either the primary or secondary containment structure or any release of hazardous waste or accumulated liquid in the secondary containment system within 24 hours, 40 C.F.R. § 265.193(c)(3), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);
- i. package, mark, and label hazardous waste containers in compliance with the requirements of Mo. Code Regs. tit. 10, 25-5.262(2)(C)1, incorporating 40 C.F.R. § 262.32 and 40 C.F.R. part 262 Subpart C;
- j. inspect hazardous waste containers weekly to identify leaks and deterioration caused by corrosion or other factors, 40 C.F.R. § 262.34(a)(1)(i), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1), referencing 40 C.F.R. § 265.174, as incorporated by reference at Mo. Code Regs. tit. 10, 25-7.265(1);
- k. properly label satellite accumulation containers with the words “Hazardous Waste” or with other words identifying the contents of the containers and the beginning date of satellite storage, as required by Mo. Code Regs. tit. 10, 25-5.262(2)(C)1. and 25-5.262(2)(C)3;
- l. properly label and date all hazardous waste on-site, 40 C.F.R. § 262.34(a)(2) and (a)(3), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);

- m. take precautions to prevent accidental ignition of ignitable waste by separating and protecting it from sources of ignition or reaction including, but not limited to, hot surfaces, sparks, and radiant heat. Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.F.(II);
- n. inspect hazardous waste tank systems daily to identify leaks and deterioration caused by corrosion or other factors, 40 C.F.R. § 262.34(a)(1)(ii), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1) and 25-5.262(2)(C)2.C.(II), referencing 40 C.F.R. § 265.195, as incorporated by reference at Mo. Code Regs. tit. 10, 25-7.265(1);
- o. document the results of the inspection of tank overfill prevention controls and of corrosion or releases of waste, 40 C.F.R. § 265.195(g), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);
- p. respond to leaks or spills from tanks by immediately ceasing use of the tank, by preventing flow or addition of waste, and by removing waste from tank system or secondary containment system, 40 C.F.R. § 265.196, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1); and
- q. maintain and operate their facility to minimize the possibility of a fire, explosion, or release of hazardous waste which could threaten human health or the environment, 40 C.F.R. § 262.34(a)(4), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1), referencing 40 C.F.R. Part 265, Subpart C, which is incorporated by reference at Mo. Code Regs. tit. 10, 25-7.265(1).

44. At the core of these requirements is the obligation to determine whether wastes are hazardous. The regulations set forth a step-wise process for characterizing wastes. 40 C.F.R.

§ 262.11, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1). First, the generator must determine if the waste is excluded from regulation under 40 C.F.R. § 261.4, as incorporated by reference at Mo. Code Regs. tit. 10, 25-4.261(1). Second, if the waste is not excluded, the generator must determine if the waste has already been determined by EPA to be hazardous, i.e., whether it is a "listed" hazardous waste set forth in Subpart D of 40 C.F.R. Part 261, which is incorporated by reference at Mo. Code Regs. tit. 10, 25-4.261(1). Listed hazardous wastes that EPA has "found to be fatal to humans in low doses," highly toxic to related animals at low doses, "or [are] otherwise causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness" are "acute hazardous wastes." Third, if the waste is not "listed," the generator must determine whether the waste fails any of the tests set forth in Subpart C of 40 C.F.R. Part 261, as incorporated by reference at Mo. Code Regs. tit. 10, 25-4.261(1) (or otherwise approved by EPA), i.e., whether it is a "characteristic" hazardous waste because it exhibits any of the characteristics of ignitability, reactivity, corrosivity, or toxicity.

E. Enforcement of the Clean Water Act, Clean Air Act, the Resource Conservation and Recovery Act, the Missouri Clean Water Law, the Missouri Air Conservation Law, and the Missouri Hazardous Waste Management Law

45. The Clean Water Act, 33 U.S.C. § 1319, authorizes the United States to commence a civil action against a source that introduces pollutants into a publicly owned treatment works in violation of the pretreatment standards.

46. In states authorized to implement their own NPDES programs and Pretreatment programs, EPA retains authority, concurrent with authorized state NPDES and Pretreatment programs, to enforce state-issued permits. 33 U.S.C. §§ 1319 and 1342(i).

47. EPA may also issue administrative orders requiring compliance with the Clean Water Act whenever EPA finds that a person is in violation of, *inter alia*, 33 U.S.C. § 1301. *See* 33 U.S.C. § 1319(a).

48. The Clean Air Act, 42 U.S.C. § 7413(a), also authorizes the United States to commence a civil action against any person who has violated, or is in violation of, the National Emissions Standard for Hazardous Air Pollutants.

49. The Resource Recovery and Conservation Act, 42 U.S.C. § 6928(a), authorizes the United States to commence a civil action against any person who has violated, or is in violation of any requirement of Sections 3001 through 3019f of the Resource Recovery and Conservation Act, 42 U.S.C. §§ 6921 through 6939f, in the United States district court in the district in which the violation occurred for appropriate relief, including a temporary or permanent injunction.

50. Pursuant to Sections 3008(a) and 3006(g) of the Resource Conservation and Recovery Act, 42 U.S.C. §§ 6928(a) and 6926(g), the United States may enforce the federally-approved Missouri hazardous waste program, as well as the federal regulations that remain effective in Missouri by filing a civil action in United States District Court.

51. A person who violates the Clean Water Act, Clean Air Act or the Resource Conservation and Recovery Act is subject to a civil penalty not to exceed \$25,000 a day for each violation. 33 U.S.C. § 1319(d); 42 U.S.C. § 7413(b); 42 U.S.C. §§ 6928(a) and (g). Under 40 C.F.R. Part 19, Adjustment of Civil Monetary Penalties for Inflation, as amended, and pursuant to 28 U.S.C. § 2461, the civil penalty amount was raised to a maximum of \$32,500 per day for each violation occurring after March 15, 2004 and before January 12, 2009 and \$37,500 for violations occurring after January 12, 2009. *See* 74 Fed. Reg. 626-01 (Jan. 7, 2009).

52. The Missouri Air Conservation Law, at Mo. Rev. Stat. § 643.151.1, makes it unlawful for any person to cause or permit any air pollution by emission of any air contaminant from any air contaminant source in violation of the Law or any rule promulgated by the Air Conservation Commission.

53. Mo. Rev. Stat. § 643.079 authorizes the Missouri Department of Natural Resources to collect fees per ton of regulated air contaminants emitted by Teva.

54. Mo. Rev. Stat. § 643.151.3 authorizes injunctive relief to prevent further violations of the Missouri Air Conservation Law and a civil penalty not to exceed \$10,000 for each day, or part thereof, the violation occurred or continues to occur.

55. The Missouri Clean Water Law, at Mo. Rev. Stat. §§ 644.051.1(3) and 644.076.1, and Mo. Code Regs. tit. 10, 20-6.100(4)(A)1 make it unlawful to introduce a pollutant into the South Fork of the Salt River, waters of the state.

56. Mo. Rev. Stat. §§ 644.051.1(3) and 644.076.1 and Mo. Code Regs. tit. 10, 20-6.100(4)(B)4 and (D) make it unlawful to fail to comply with the pretreatment standards and to release pollutants at a rate and/or concentration that interfere with the operation of a Publicly Owned Treatment Works.

57. Mo. Rev. Stat. §§ 644.051.1(1) and 644.076.1 make it unlawful to cause pollution to the South Fork of the Salt River, which are waters of the state, or place or caused or permitted to be placed a water contaminant in a location where it is reasonably certain to cause pollution of waters of the state.

58. Mo. Rev. Stat. §§ 644.051.1(2) and 644.076.1 and Mo. Code Regs. tit. 10, 20-7.031(3) make it unlawful to discharge water contaminants into waters of the state which reduce

the quality of such waters below the Water Quality Standards established by the Missouri Clean Water Commission.

59. Mo. Rev. Stat. § 644.096 authorizes the Missouri Department of Natural Resources to collect from Teva actual damages, including costs and expenses of restoring waters of the state to their condition as they existed before the violation.

60. Mo. Rev. Stat. § 644.076.1 authorizes injunctive relief to prevent further violations of the Missouri Clean Water Law and a civil penalty not to exceed \$10,000 for each day, or part thereof, the violation occurred or continues to occur.

61. The Missouri Hazardous Waste Management Law, at Mo. Rev. Stat. § 260.425.1, makes it unlawful for any person to violate the provisions of the Law, including its implementing regulations.

62. Mo. Rev. Stat. § 260.380 authorizes the Missouri Department of Natural Resources to collect from Teva an annual fee based on tons of hazardous waste generated.

63. Mo. Rev. Stat. § 260.425 authorizes injunctive relief to prevent further violations of the Missouri Hazardous Waste Management Law and a civil penalty not to exceed \$10,000 for each day, or part thereof, the violation occurred or continues to occur.

GENERAL ALLEGATIONS

A. Teva's Mexico Facility is Subject to Subpart GGG.

64. At all times relevant to this action, Teva's Mexico Facility was a "stationary source" as that term is defined in the Clean Air Act. 42 U.S.C. § 7412(a)(3).

65. At all times pertinent to this action, Teva's Mexico Facility was a "major source" of "hazardous air pollutants" as those terms are defined in the Clean Air Act. 42 U.S.C. § 7412(a).

66. At all times relevant to this action, Teva's Mexico Facility was an "affected source" as defined in 40 C.F.R. § 63.1250(a).

67. At all times pertinent to this action, Teva manufactured pharmaceutical products (as defined in 40 C.F.R. § 63.1251), including antibiotics such as amoxicillin and cephalexin, at Teva's Mexico Facility.

68. At all times pertinent to this action, Teva's Mexico Facility was a "pharmaceutical manufacturing operation" as that term is defined at 40 C.F.R. § 63.1251.

69. At all times pertinent to this action, Teva used hazardous air pollutants (as defined at 42 U.S.C. § 7412), including methylene chloride (dichloromethane), triethylamine, hydrochloric acid, toluene, methanol, and dimethylformamide, at Teva's Mexico Facility.

B. Teva Violated the Requirements of Subpart GGG.

70. EPA inspected Teva's Mexico Facility in June 2007.

71. The regulations require Teva to install tightly fitted covers and seals on drain systems and junction boxes and vent emissions to a process or control device. 40 C.F.R. § 63.1256(e). At the time of an EPA inspection in June 2007, the cover to the lift station that conveys water from the process units to an above ground storage tank was not properly sealed or vented. There were visible gaps in the lid around the pipes and fixtures passing through the lid. Teva's failure to install tightly fitted covers and seals on the lift station cover violated 40 C.F.R. § 63.1256(e).

72. Under Subpart GGG, Teva was required to analyze its wastewater or designate wastewater streams as "affected wastewater" containing hazardous air pollutants. *See* 40 C.F.R. § 63.1256(a). Teva was required to manage each "such wastewater stream . . . in accordance with all applicable emission suppression requirements . . . and with the treatment requirements in

paragraph (g) of this section.” *Id.* § 63.1256(a)(1)(ii)(B). Teva has elected to comply with paragraph (g)(11), which provides that “[t]he owner or operator of a new or existing source using biological treatment for any affected wastewater shall reduce the mass of total soluble and partially soluble HAP sent to that biological treatment unit by at least 95 percent.” Accordingly, Teva was required to manage the affected wastewater streams by reducing total HAPs by at least 95%. Teva made a faulty determination that its wastewater treatment plant was achieving the required 95% HAP destruction efficiency. In fact, Teva’s actual HAP destruction efficiency was well below the required 95%. Therefore, between at least February 2004 and June 2010, Teva violated Subpart GGG both by failing to control HAPs in its wastewater and by failing to properly calculate the destruction efficiency of its treatment plant.

73. Subpart GGG, at 40 C.F.R. § 63.1254(a), allows a source to choose one of two compliance methods for its vents. In its notification of compliance, Teva has selected the compliance method that provides that “[a]ctual HAP emissions from the sum of all process vents within a process must not exceed 900 kilograms (kg) in any 365-day period.” *Id.* at § 63.1254(a)(2).

74. Subpart GGG then requires a specific demonstration of compliance with the 900 kg limit, setting forth at 40 C.F.R. § 1257(d)(1)(i) that the owner or operator of the affected source must demonstrate that “the actual emissions of HAP from the sum of all process vents within a process is less than or equal to 900 kg/yr.” In performing its initial and periodic compliance demonstrations, however, Teva violated the regulation by not including all hazardous air pollutants in its calculations. Specifically, Teva omitted hydrochloric acid from its calculations for its initial compliance demonstration and for its periodic compliance

demonstrations for at least January 2006, August 2006, January 2007, July 2007, and February 2008.

75. Teva uses carbon adsorption to control emissions from the amoxicillin process and is, therefore, required by 40 C.F.R. § 63.1258(b)(1)(iv)(B) to monitor and record the regeneration frequency, temperature to which the bed is heated during regeneration, temperature to which the bed is cooled, and regeneration stream flow of the carbon adsorber. In TEVA's February 2004 Notice of Compliance Status Report, TEVA stated that it would monitor and record all parameter values in 40 C.F.R. § 63.1258(b)(1)(iv). TEVA failed to monitor and record those values.

76. In at least June 2007, Teva failed to cap open ended lines subject to the LDAR requirements. Specifically, 40 C.F.R. § 63.1255(d) requires that "[e]ach open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve." This cap, blind flange, plug, or second valve "shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair." In June 2007, EPA inspectors observed approximately 20 open-ended lines not equipped with a cap, blind flange, plug, or second valve.

77. Teva is required to identify all equipment valves, connectors, instrumentation systems, and other specified equipment that are intended to operate in organic hazardous air pollutant service for 300 hours or more during the calendar year within an affected source. 40 C.F.R. § 63.1255(a)(7). To comply with this requirement, Teva must ensure that the equipment "can be distinguished readily from equipment that" is not subject to the LDAR requirements. *Id.* During the 2007 inspection, EPA determined that Teva had failed to adequately identify approximately 35 pieces of equipment that were subject to the requirements and identified

approximately 20 pieces of equipment that were not physically present at Teva's Mexico Facility. Teva also failed to monitor that the 35 pieces equipment omitted from its drawings for leaks as required by the regulations.

78. The regulations at 40 C.F.R. § 63.1255(c)(5)(iv) state that each pump with a dual mechanical system that includes a barrier fluid system is exempt from LDAR monitoring requirements if, *inter alia*, the pump is checked by visual inspection each calendar week for indications of liquids dripping from the pump seal. 40 C.F.R. § 63.1255(g)(3) requires that the weekly visual inspection be documented and that Teva maintain the documentation for a period of two years. At the time of EPA's inspection in 2007, TEVA did not have any records of their visual inspection of at least pumps P-617 and P-606.

79. Teva also failed to identify and monitor approximately 250 components from the regenerative thermal oxidizer (RTO) in the LDAR program from at least April 5, 2004, until December 12, 2006. TEVA stated in its January 30, 2007, Periodic Report that it failed to include 250 components associated with the RTO system collection headers in its LDAR monitoring program. TEVA did not monitor these components until December 12, 2006. Two pieces of equipment were found to be leaking during the first LDAR monitoring event.

80. Further, in 2006 and 2007, Teva located approximately 13 leaking valves, but failed to complete the repairs as required by the regulations. Under 40 C.F.R. § 63.1251, "repaired" means that: 1) the equipment is adjusted/alterd to eliminate the leak, and; 2) unless otherwise specified in § 63.1255, monitored to verify that emissions are below the appropriate leak definition. In order to satisfy the second prong of the "repaired" definition, 40 C.F.R. § 63.1255(e)(7)(iii) requires TEVA to monitor leaking valves within 3 months of repair. A review of TEVA's LDAR monitoring database revealed that TEVA failed to monitor repaired valves

within 3 months of repair. TEVA recorded the date that the valve was leaking and also recorded the date the valve was repaired below the applicable leak definition. However, TEVA failed to monitor at least 7 valves within 3 months of the repair date. Accordingly, those valves were not “repaired” as required by the regulations.

81. From at least October 21, 2002, to at least June 15, 2007, TEVA failed to monitor “difficult to monitor valves” at the required frequency. Pursuant to 40 C.F.R. § 63.1255(f)(3), equipment, including valves, designated as “difficult to monitor” must have a written plan that requires monitoring of the equipment at least once per calendar year or on the periodic monitoring schedule otherwise applicable to the group of processes in which equipment is located, whichever is less frequent. Teva identified as “difficult to monitor” valves from a group of processes that were subject to monthly monitoring. Therefore, these valves were required to be monitored on an annual basis. Once TEVA placed valves on the difficult to monitor list, it improperly took them out of its LDAR monitoring program, and monitoring did not occur past that date. As a result, TEVA failed to monitor 11 difficult to monitor valves between January 1, 2004, and approximately September 2008.

C. Teva’s Discharges of Wastewater are Subject to the Clean Water Act and the Missouri Clean Water Law.

82. At all times relevant to this action, the City of Mexico operated a POTW subject to an NPDES permit issued by MDNR. At all relevant times, that POTW discharged to the South Fork of the Salt River, a perennial water and tributary of Mark Twain Lake. The Lake is a man made impoundment of water that covers 18,000 acres and is used in part for recreation purposes including boating.

83. At all times relevant to this action, Teva discharged to the City of Mexico's POTW through a "point source" as defined in 33 U.S.C. § 1362(14) and Mo. Rev. Stat. § 644.016(14).

84. At all times relevant to this action, Teva's Mexico Facility was subject to the categorical pretreatment standards for pharmaceutical manufacturing found at 40 C.F.R. Part 439.

85. At all times relevant to this action, Teva was a "Significant Industrial User" of the City of Mexico's POTW, as that term is defined in 40 C.F.R. § 403.3(t), because it discharged in excess of 90,000 gallons per day of process wastewater into the City of Mexico's POTW. Teva is also a significant industrial user because it is subject to Federal Categorical Pretreatment Standards, specifically, 40 C.F.R. Part 439.

86. The City of Mexico has issued a pretreatment permit, known as an Industrial User Permit, to Teva governing its discharges to the POTW. At all times relevant to this action, Teva was subject to local limits on pollutants discharged to the POTW, including limits on the biological oxygen demand (BOD), and total suspended solids (TSS), and ammonia discharged to the POTW.

D. Teva Violated the Clean Water Act and the Missouri Clean Water Law.

87. Teva's Industrial User Permit requires Teva to monitor for BOD, TSS, and ammonia once per week. Teva is required to submit monitoring results on the twenty-eighth day of each month. Teva reported over 905 daily equivalent violations of its local limits, each of which is a violation of the Clean Water Act and the Missouri Clean Water Law.

88. Teva produces various antibiotics through fermentation and solvent recovery. As such, Teva is subject to the "Fermentation Products" requirements of 40 C.F.R. Part 439, Subpart

A. The City of Mexico incorporated limits for the four regulated solvents that Teva uses: acetone, toluene, methylene chloride, and triethylamine, in Teva's Industrial User Permit. Teva's Industrial User Permit requires Teva to conduct weekly sampling for acetone and monthly sampling for toluene, methylene chloride, and triethylamine. Teva's records demonstrate that it had 811 daily equivalent violations of its categorical limits, each of which is a violation of the Clean Water Act.

89. The City of Mexico is required by its NPDES permit to report effluent violations to MDNR in writing and provide a description of the discharge and the cause of noncompliance. The City has reported hundreds of daily equivalent violations of its BOD, TSS and ammonia effluent limits that the City attributes to Teva's discharges. These violations align with Teva's violation of its local limits. In all, there were more than twelve months in which Teva's discharges caused or contributed to the City's NPDES permit violations.

90. In November 2008, the operator for the City's treatment plant saw Teva discharging a green effluent into the treatment plant. Upon investigation, the City determined that its own discharge to the South Fork of the Salt River was green, in violation of the narrative water quality standards contained in the City's own permit and Teva's Industrial User Permit. The City's conclusion that Teva caused or contributed to the violations of the City's permit was confirmed by both MDNR and EPA.

91. On December 10, 2008, the City issued an order stopping all wastewater from Teva from reaching the City's plant (with very limited exceptions). In response to the order, Teva installed a temporary carbon filtration system and began discharging again. Within days, the City's wastewater had lost its green hue. A similar pattern was repeated in January 2009.

E. Teva's Mexico Facility is Subject to the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law.

92. At all times relevant to this action, Teva's Mexico Facility was a "facility" as that term is defined in 42 U.S.C. § 6903, 40 C.F.R. § 260.10 (as incorporated by reference at Mo. Code Regs. tit. 10,25-3.260) and Mo. Rev. Stat. § 260.360, and a "hazardous waste facility" as that term is defined in Mo. Rev. Stat. § 260.360(12).

93. At all times relevant to this action, Teva was a "generator" of "hazardous wastes" as those terms are defined in 42 U.S.C. § 6903, 40 C.F.R. § 260.10 (as incorporated by reference at Mo. Code Regs. tit. 10, 25-3.260) and Mo. Rev. Stat. § 260.360, at Teva's Mexico Facility.

94. Teva submitted notification as a Large Quantity Generator at Teva's Mexico Facility on February 13, 1998. At all times relevant to this action, Teva was a Large Quantity Generator at Teva's Mexico Facility under 40 C.F.R. § 261.5, as incorporated by reference at Mo. Code Regs. tit. 10, 25-4.261.

F. Teva violated the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law.

95. MDNR inspected Teva's Mexico Facility in May 2007 and November 2009.

Failure to Determine Waste Was Hazardous

96. During the MDNR inspection in 2009, a Teva representative acknowledged that fluorescent lamps from the facility were disposed in the general trash. Some of the fluorescent lamps that were disposed of in the general trash contained mercury and were hazardous waste (D009).

97. At all times relevant to this action, Teva operated a distillation unit that processes spent methylene chloride. Over one thousand tons of still bottoms from the methylene chloride

distillation unit were sent to Teva's wastewater treatment plant from at least March 2005 until January 2009. Methylene chloride is a listed hazardous waste for toxicity (F002). Teva did not conduct a hazardous waste determination on the methylene chloride still bottoms. After January 2009, Teva ceased sending methylene chloride still bottoms to the wastewater treatment plant and began manifesting them to a hazardous waste disposal facility.

98. At all times relevant to this action, Teva generated sludge from its wastewater treatment plant. Until approximately January 2009, Teva discharged hazardous methylene chloride still bottoms to Teva's wastewater treatment plant. Teva did not conduct a hazardous waste determination on the wastewater treatment plant sludge. The wastewater treatment plant sludge was generated from the treatment of methylene chloride, which is a listed hazardous waste for toxicity (F002), causing the sludge to be a hazardous waste. From at least 1995 until January 2009, an average of approximately 1.2 million gallons per year of hazardous wastewater treatment plant sludge was removed from Teva's wastewater treatment plant and disposed of on land.

Illegal Storage of Hazardous Waste Without a TSD Permit

99. Teva also failed to comply with certain hazardous waste generator requirements for EPA (large quantity) generators, including:

- a. Failure to date six containers of hazardous waste that were stored inside a flammable liquids storage cabinet. At the time of the 2009 MDNR inspection, the six containers of hazardous waste were not dated as required by 40 C.F.R. § 262.34(a)(2), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1). In addition, Teva failed to inspect these hazardous waste containers weekly to identify leaks and deterioration

caused by corrosion or other factors in violation of 40 C.F.R. § 262.34(a)(1)(i), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1), referencing 40 C.F.R. § 265.174, as incorporated by reference at Mo. Code Regs. tit. 10,25-7.265(1);

- b. Tank T-813 was not labeled with the words “Hazardous Waste” at the time of the 2009 MDNR inspection, as required by 40 C.F.R. § 262.34(a)(3), as incorporated by reference at Mo. Code Regs. tit. 10,25-5.262(1).
- c. At the time of the 2009 MDNR inspection, the external liner of the secondary containment system for hazardous waste storage tanks T-825, T-826, T-827 and T-1403 was not free of cracks and gaps, in violation of 40 C.F.R. 262.34(a)(1)(ii) referencing 40 C.F.R. § 265.193(e)(1)(iii), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1).
- d. At the time of the 2009 MDNR inspection, hazardous waste storage tank T-813 was located in a containment structure that was not constructed of or lined with an impervious waste compatible material, in violation 40 C.F.R. 262.34(a)(1)(ii) referencing 40 C.F.R. 262.193(c)(1), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1).
- e. At the time of the 2009 MDNR inspection, hazardous waste storage tank T-813 was installed directly on a concrete pad within a containment structure. The containment system for hazardous waste storage tank T-813 was not equipped with a leak detection system capable of detecting a leak within 24 hours, as required by 40 C.F.R. 262.34(a)(1)(ii) referencing

40 C.F.R. 265.193(c)(3), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1).

- f. From at least May 1, 2009, until at least November 24, 2009, Teva failed to document the results of the inspection of tank overfill prevention controls, by failing to document presence of tank high level alarms and tanks that were filled above capacity in tank inspection reports, as required by 40 C.F.R. § 262.34(a)(1)(ii) referencing 40 C.F.R. § 265.195(g), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1).
- g. On February 2-4, 2009, March 31- April 7, 2009, July 23-28, 2009, and October 14, 2009-November 23, 2009, the fill line to tank T-826 was leaking. On July 20-28, 2009, the fill line to T-825 was leaking. During each of these leak events, Teva failed to respond to leaks or spills from tank systems by immediately ceasing use of the tank system by preventing flow or addition of waste, and failed to remove waste from the tank system or secondary containment system within 24 hours or as soon as practicable to prevent further release of hazardous waste, as required by 40 C.F.R. § 262.34(a)(1)(ii) referencing 40 C.F.R. § 265.196, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1).
- h. At the time of the May 2007 MDNR inspection, until at least February 2010, hazardous spent sulfuric acid was stored in tank T-1403. The containment structure for tank T-1403 is constructed with a hole that is approximately 12 inches in diameter that would allow a spill from T-1403 to enter the secondary containment for tanks that store the following

hazardous wastes: methylene chloride (T-827); toluene, methylene chloride and methanol (T-826); and dimethylformamide, acetone and isopropyl alcohol (T-825). The hole in the secondary containment for tank T-1403 would allow a spill of hazardous waste to flow into the secondary containment for tanks T-825, T-826, T-827 and vice versa. Upon information and belief, this manner of storage of incompatible materials presents the potential to generate fire, explosion, violent reaction or toxic gases, in violation of 40 C.F.R. § 262.34(a)(1)(ii) referencing 40 C.F.R. § 265.199(a), referencing 40 C.F.R. § 265.17(b), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1).

- i. Beginning on at least May 1, 2009, Teva stored spent sulfuric acid, a hazardous waste, in tank T-813. Teva failed to obtain a written assessment reviewed and certified by a qualified Professional Engineer attesting that tank T-813 has sufficient structural integrity and is acceptable for storing and treating hazardous waste, prior to placement of hazardous waste into the tank system, as required by 40 C.F.R. § 262.34(a)(1)(ii) referencing 40 C.F.R. § 265.192(a), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1). In addition, Teva failed to conduct daily inspections of T-813 and its containment system, as required by 40 C.F.R. § 262.34(a)(1)(ii) referencing 40 C.F.R. § 265.195, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1), and by Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.C.(II), as incorporated by reference at Mo. Code Regs. tit. 10, 25-7.265(1).

- j. Beginning on July 13, 2009, hazardous waste tank T-813 was filled above capacity with hazardous spent sulfuric acid. The volume of hazardous spent sulfuric acid remained above the capacity of T-813 until at least August 31, 2009. Because the tank was filled above capacity, Teva failed to maintain and operate their facility to minimize the possibility of a release of hazardous waste which could threaten human health or the environment, in violation of 40 C.F.R. § 262.34(a)(4) referencing 40 C.F.R. Part 265, Subpart C, which is incorporated by reference at Mo. Code Regs. tit. 10, 25-7.265(1) and Mo. Code Regs. tit. 10, 25-5.262(1).

Failure to Comply with Missouri Pretransport, Containerization, and Labeling Requirements

100. Teva also failed to comply with Missouri's Pretransport, Containerization, and Labeling Requirements, applicable to generators of hazardous waste, including:

- a. Failure to label, package, mark and inspect six containers of hazardous waste that were stored inside a flammable liquids storage cabinet. At the time of the 2009 MDNR inspection, the six containers of hazardous waste were not labeled, packaged, and marked as required by Mo. Code Regs. tit. 10, 25-5.262(2)(C)1, incorporating 40 C.F.R. § 262.32 and 40 C.F.R. part 262 Subpart C, and were not inspected on a weekly basis as required by Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.C.(I) and (II) referencing 40 C.F.R. § 265.174.
- b. Failure to mark the beginning date of satellite storage for hazardous waste that was being stored in at least four satellite accumulation containers in

the QC lab. At the time of the 2009 MDNR inspection, the satellite accumulation containers were not marked with the beginning date of satellite storage as required by Mo. Code Regs. tit. 10, 25-5.262(2)(C)1. and 25-5.262(2)(C)3.

- c. At the time of the 2009 MDNR inspection an electric heater was operated in close proximity to ignitable hazardous waste in the satellite accumulation area of the QC lab. Teva failed to take precautions to prevent accidental ignition of ignitable waste by operation of Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.F.(II).
- d. At the time of the 2009 MDNR inspection, the containment system for hazardous waste storage tanks T-825, T-826, T-827 and T-1403 was not equipped with an impervious coating that was free of cracks and gaps, as required by Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.E. referencing Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.D.(III)(a).

Offering Hazardous Waste for Transport Without a Manifest

101. From at least 1995 until June 2008, an average of approximately 1.2 million gallons per year of hazardous wastewater treatment plant sludge was removed from Teva's wastewater treatment plant and shipped off-site. The City of Mexico, Missouri hauled Teva's hazardous wastewater treatment plant sludge during this time period, at 1,500 gallons per load, equaling approximately 800 shipments of hazardous waste per year. For each shipment of hazardous wastewater treatment plant sludge during this time period, Teva failed to use a hazardous waste transporter with a valid hazardous waste license, failed to provide a manifest to the transporter for each load of hazardous waste transported from the premises where it was

generated, and failed to transport such waste only to an authorized transport, storage, or disposal facility, in violation of 40 C.F.R Part 262, Subpart B, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1) and modified by Mo. Code Regs. tit. 10, 25-5.262(2)(B); Mo. Rev. Stat. §§ 260.380.1(5), (6), and (7).

FIRST CLAIM FOR RELIEF

Violations of the Clean Air Act and the Missouri Air Conservation Law

102. The allegations of the foregoing paragraphs are incorporated herein by reference.

103. As described more fully above, Subpart GGG, incorporated by reference at Mo. Code Regs. tit. 10, 10-6.075, imposes specific requirements to monitor and control emissions of hazardous air pollutants which Teva violated, including those identified in the following subparagraphs.

- a. Teva failed to install tightly fitted covers and seals on drain systems and junction boxes and vent emissions to a process or control device as required by 40 C.F.R. § 63.1256(e).
- b. Teva failed to achieve a HAP destruction efficiency of 95% of hazardous air pollutants in its wastewater stream and failed to properly calculate the destruction efficiency of its wastewater treatment system as required by 40 C.F.R. § 63.1256.
- c. Teva violated 40 C.F.R. § 1257(d)(1)(i) when it failed to include all actual emissions of hazardous air pollutants from process vents in its demonstration of compliance with the requirements of 40 C.F.R. § 63.1254(a), during at least January 2006, August 2006, January 2007, July 2007, and February 2008.

- d. Between at least August 2006 and at least October 2007, Teva failed to monitor and record certain operating conditions for its carbon adsorption equipment used to control emissions from the amoxicillin process, in violation of 40 C.F.R. § 63.1258(b)(1)(iv)(B).
- e. Teva failed to cap open ended lines subject to the LDAR requirements in violation of 40 C.F.R. § 63.1255(d), as identified during EPA's 2007 inspection.
- f. Teva failed to identify and properly monitor certain equipment subject to the LDAR requirements, as identified during EPA's 2007 inspection, thereby violating 40 C.F.R. § 63.1255(a)(7).
- g. Teva failed to conduct weekly visual inspection of at least pumps P-617 and P-606 in at least 2007, in violation of 40 C.F.R. § 63.1255(c)(5)(iv).
- h. Teva failed to identify and monitor approximately 250 components from the regenerative thermal oxidizer (RTO) in the LDAR program from approximately April 5, 2004, until approximately December 12, 2006.
- i. Teva failed to properly complete the repair on approximately 13 leaking valves, in violation of 40 C.F.R. § 63.1255(e)(7)(iii).
- j. Teva failed to monitor "difficult to monitor" valves at the required frequency from at least October 21, 2002, to at least September 2008 in violation of 40 C.F.R. § 63.1255(f)(3).

104. Teva failed to pay air emission fees to the State from 2005 to 2010 for excess emissions of HAPs from the wastewater treatment plant in violation of Mo. Rev. Stat. § 643.079.

105. Each day that Teva violated the requirements of Subpart GGG and Mo. Code Regs. tit. 10, 10-6.075 as set forth above is a separate violation of the Clean Air Act and the Missouri Air Conservation Law.

106. As provided in the Clean Air Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, the violations set forth above subject Teva to injunctive relief and civil penalties of up to \$32,500 per day for each violation that occurred between March 15, 2004, and January 12, 2009, and up to \$37,500 per day for each violation that occurred after January 12, 2009.

107. As provided in the Missouri Air Conservation Law, Mo. Rev. Stat. § 643.079, Teva is liable to the Missouri Department of Natural Resources for payment of air emission fees.

108. As provided in the Missouri Air Conservation Law, Mo. Rev. Stat. § 643.151.3, the violations set forth above subject Teva to injunctive relief and civil penalties of up to \$10,000 per day for each violation.

109. Unless enjoined, Teva's violations will continue or recur.

SECOND CLAIM FOR RELIEF
Violations of the Clean Water Act and the Missouri Clean Water Law

110. The allegations of the foregoing paragraphs are incorporated herein by reference.

111. On numerous occasions between January 2006 and at least April 2009, Teva's discharges to the City of Mexico's POTW were in violation of the local limits for BOD, TSS, and ammonia established in Teva's industrial user permit.

112. On numerous occasions between January 1, 2006, and at least November 2008, Teva's discharges to the City of Mexico's POTW were in violation of the pharmaceutical category categorical pretreatment standards and equivalent requirements incorporated into Teva's Industrial User Permit for acetone, toluene, triethylamine and methylene chloride.

113. On or before November 19, 2009, Teva's green effluent passed through and/or interfered with the City of Mexico's POTW into the South Fork of the Salt River. This violation continued until at least December 10, 2009.

114. Teva's discharges to the POTW between January 1, 2006, and at least November 2008, including those in violation of its Industrial User Permit and the categorical pretreatment standards, alone or in conjunction with the discharge or discharges from other sources, have caused the City of Mexico to violate the final effluent limitations and other conditions of its NPDES permit.

115. Teva's discharges to the POTW between January 1, 2006, and at least November 2008, including those in violation of its industrial user permit and the categorical pretreatment standards, which alone or in conjunction with the discharge or discharges from other sources have caused the City to incur the violations stated above, constitute interference and/or pass through at the POTW.

116. Teva's discharges to the POTW violated 33 U.S.C. §§ 1311 and 1317, 40 C.F.R. §§ 403.5 and 439, Mo. Rev. Stat §§ 644.051.1(3) and 644.076.1, and Mo. Code Regs. tit. 10, 20-6.100(4)(A)1, (B)4 and (D).

117. Pursuant to 33 U.S.C. § 1319(b) and (d), Teva is liable for civil penalties of up to \$32,500 per day for each violation that occurred between March 15, 2004 and January 12, 2009 and up to \$37,500 per day for each violation that occurred after January 12, 2009.

118. Pursuant to the Missouri Clean Water Law, Mo. Rev. Stat. § 644.096, Teva is liable for actual damages, including costs and expenses of restoring waters of the state to their condition as they existed before the violation.

119. Pursuant to the Missouri Clean Water Law, Mo. Rev. Stat. § 644.076.1, Teva is liable for civil penalties of up to \$10,000 per day for each violation.

120. Unless enjoined, Teva's violations will continue or recur.

THIRD CLAIM FOR RELIEF

**Violations of the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law
(Failure to Determine Waste Was Hazardous)**

121. The allegations of the foregoing paragraphs are incorporated herein by reference.

122. As described more fully above, pursuant to 40 C.F.R. § 262.11 and Mo. Code Regs. tit. 10, 25-5.262(1), any person who generates a solid waste must determine if that waste is a hazardous waste, using prescribed methods.

123. As of the time of the 2009 MDNR inspection, Teva failed to conduct a hazardous waste determination on the fluorescent lamp solid waste that had been generated by the Teva Mexico Facility.

124. From at least March 2005 until January 2009, Teva failed to conduct a hazardous waste determination on solid waste still bottoms generated by the methylene chloride distillation unit at the Teva Mexico Facility.

125. From at least March 2005 until January 2009, Teva failed to conduct a hazardous waste determination on solid waste sludge from the Teva Mexico Facility's wastewater treatment plant.

126. Teva has violated the requirements of Subchapter III of the Resource Conservation and Recovery Act and Mo. Rev. Stat. § 260.380, by failing to conduct hazardous waste determinations on solid waste listed in paragraphs 123, 124 and 125, above, in accordance with 40 C.F.R. § 262.11, incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1).

127. Pursuant to Section 3008(a) and (g) of the Resource Conservation and Recovery Act, 42 U.S.C. 6928(a) and (g), Teva is liable for civil penalties of up to \$32,500 per day for each violation that occurred between March 15, 2004 and January 12, 2009 and up to \$37,500 per day for each violation that occurred after January 12, 2009.

128. Pursuant to the Missouri Hazardous Waste Management Law, Mo. Rev. Stat. § 260.425.1, Teva is liable for civil penalties for up to \$10,000 per day for each violation.

129. Unless enjoined, Teva's violations will continue or recur.

FOURTH CLAIM FOR RELIEF

**Violations of the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law
(Illegal Storage of Hazardous Waste Without a TSD Permit)**

130. The allegations of the foregoing paragraphs are incorporated herein by reference.

131. 40 C.F.R. § 262.34(a), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1) and modified at Mo. Code Regs. tit. 10, 25-5.262(2)(C).2, allows Large Quantity Generators to accumulate hazardous waste on-site for 90 days or less without obtaining a permit or interim status, subject to the requirements that they:

- a. Mark each hazardous waste storage container with the date upon which each period of accumulation began. 40 C.F.R. § 262.34(a)(2), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);
- b. Inspect hazardous waste containers weekly to identify leaks and deterioration caused by corrosion or other factors, 40 C.F.R. § 262.34(a)(1)(i), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1), referencing 40 C.F.R. § 265.174, as incorporated by reference at Mo. Code Regs. tit. 10, 25-7.265(1);

- c. Clearly mark each container with the words "Hazardous Waste." 40 C.F.R. § 262.34(a)(3), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1);
- d. Place all waste in tanks that have been assessed by a qualified Professional Engineer; are equipped with secondary containment designed, installed and operated to prevent migration of wastes out of the system; equipped with secondary containment that is capable of detecting and collecting releases and accumulated liquids; are equipped with controls and practices to prevent spills and overflows from tank or secondary containment systems; and are inspected at least daily. 40 C.F.R. § 262.34(a)(1)(ii) referencing 40 C.F.R. § 265 Subpart J, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1); and
- e. Comply with the requirements for owners or operators in Subparts C and D of 40 C.F.R. part 265, including, inter alia, operate and maintain the facility to minimize the possibility of an emergency. 40 C.F.R. § 262.34(a)(4), as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1).

132. If an owner or operator of a Large Quantity Generator accumulates waste for more than 90 days, or if these requirements are not met, the owner or operator is not allowed to store hazardous waste for any period of time. 42 U.S.C. § 6925(a) and Mo. Rev. Stat. § 260.390(1), and their implementing regulations require the owner and/or operator to obtain a TSD permit or interim status for the facility in order to store hazardous waste.

133. Defendants failed to comply with applicable requirements found at 40 C.F.R. § 262.34, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1), including those listed in paragraph 131, above.

134. Teva has not obtained a hazardous waste TSD permit or interim status for Teva's Mexico Facility.

135. Teva has violated Section 3005 of the Resource Conservation and Recovery Act, 42 U.S.C. § 6925, and Mo. Rev. Stat. §§ 260.390 and 260.395, by owning and/or operating a hazardous waste storage facility without a permit or interim status.

136. Pursuant to Section 3008(a) and (g) of the Resource Conservation and Recovery Act, 42 U.S.C. 6928(a) and (g), Teva is liable for civil penalties of up to \$32,500 per day for each violation that occurred between March 15, 2004 and January 12, 2009 and up to \$37,500 per day for each violation that occurred after January 12, 2009.

137. Pursuant to the Missouri Hazardous Waste Management Law, Mo. Rev. Stat. § 260.425.1, Teva is liable for civil penalties for up to \$10,000 per day for each violation.

138. Unless enjoined, Teva's violations will continue or recur.

FIFTH CLAIM FOR RELIEF
Violations of the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law
(Failure to Comply with Missouri Pretransport, Containerization, and Labeling Requirements)

139. The allegations of the foregoing paragraphs are incorporated herein by reference.

140. A generator of hazardous waste must comply with the pretransport, containerization, and labeling requirements of Mo. Code Regs. tit. 10, 25-5.262(2)(C), as required by Mo. Code Regs. tit. 10, 25-5.262(2).

141. The pretransport, containerization, and labeling requirements of Mo. Code Regs. tit. 10, 25-5.262(2)(C) require, inter alia, generators of hazardous waste who accumulate waste on-site for any period to:

- a. utilize containment systems for tanks with impervious coatings that are free from gaps or cracks, Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.E. referencing Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.D.(III)(a);
- b. package, mark, and label hazardous waste containers in compliance with the requirements of Mo. Code Regs. tit. 10, 25-5.262(2)(C)1, incorporating 40 C.F.R. § 262.32 and 40 C.F.R. part 262 Subpart C;
- c. properly label satellite accumulation containers with the words “Hazardous Waste” or with other words identifying the contents of the containers and the beginning date of satellite storage, as required by Mo. Code Regs. tit. 10, 25-5.262(2)(C)1. and Mo. Code Regs. tit. 10, 25-5.262(2)(C)3; and
- d. take precautions to prevent accidental ignition of ignitable waste by separating and protecting it from sources of ignition or reaction including, but not limited to, hot surfaces, sparks, and radiant heat, Mo. Code Regs. tit. 10, 25-5.262(2)(C)2.F.(II).

142. Teva did not comply with all of the requirements of Mo. Code Regs. tit. 10, 25-5.262(2)(C), including those set forth in Paragraph 141, above, at Teva’s Mexico Facility.

143. Pursuant to Section 3008(a) and (g) of the Resource Conservation and Recovery Act, 42 U.S.C. 6928(a) and (g), Teva is liable for civil penalties of up to \$32,500 per day for

each violation that occurred between March 15, 2004 and January 12, 2009 and up to \$37,500 per day for each violation that occurred after January 12, 2009.

144. Pursuant to the Missouri Hazardous Waste Management Law, Mo. Rev. Stat. § 260.425.1, Teva is liable for civil penalties for up to \$10,000 per day for each violation.

145. Unless enjoined, Teva's violations will continue or recur.

SIXTH CLAIM FOR RELIEF

**Violations of the Resource Conservation and Recovery Act and the Missouri Hazardous Waste Management Law
(Offering Hazardous Waste for Transport Without a Manifest)**

146. The allegations of the foregoing paragraphs are incorporated herein by reference.

147. Hazardous waste generators that offer their hazardous waste for off-site treatment, storage or disposal must use a hazardous waste transporter with a valid hazardous waste license, provide a manifest to the transporter for each load of hazardous waste transported from the premises where it was generated, and transport such waste only to an authorized transport, storage, or disposal facility. 40 C.F.R Part 262, Subpart B, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1) and modified by Mo. Code Regs. tit. 10, 25-5.262(2)(B); Mo. Rev. Stat. §§ 260.380.1(5), (6), and (7).

148. Teva offered its hazardous waste for off-site treatment, storage or disposal in violation of the requirements of the Missouri regulations regarding manifesting and proper shipment of hazardous waste in violation of 40 C.F.R Part 262, Subpart B, as incorporated by reference at Mo. Code Regs. tit. 10, 25-5.262(1) and modified by Mo. Code Regs. tit. 10, 25-5.262(2)(B); Mo. Rev. Stat. §§ 260.380.1(5), (6), and (7).

149. Pursuant to Section 3008(a) and (g) of the Resource Conservation and Recovery Act, 42 U.S.C. 6928(a) and (g), Teva is liable for civil penalties of up to \$32,500 per day for

each violation that occurred between March 15, 2004 and January 12, 2009 and up to \$37,500 per day for each violation that occurred after January 12, 2009.

150. Pursuant to the Missouri Hazardous Waste Management Law, Mo. Rev. Stat. § 260.380, Teva is liable to the Missouri Department of Natural Resources for payment of hazardous waste fees and taxes.

151. Pursuant to the Missouri Hazardous Waste Management Law, Mo. Rev. Stat. § 260.425.1, Teva is liable for civil penalties for up to \$10,000 per day for each violation.

152. Unless enjoined, Teva's violations will continue or recur.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, the United States of America and the State of Missouri, pray that this Court:

1. Enjoin Teva from operating Teva's Mexico Facility in violation of the Clean Air Act and Subpart GGG, the Missouri Air Conservation Law, the Clean Water Act, the Missouri Clean Water Law, its industrial user permit, the pretreatment standards, the Resource Conservation and Recovery Act, and the Missouri Hazardous Waste Management Law.

2. Pursuant to 33 U.S.C. § 1319(b) and (d), 42 U.S.C. § 7413(b), 42 U.S.C. 6928(a) and (g), and 40 C.F.R. Part 19, assess civil penalties against Teva of up to \$32,500 per day for each violation that occurred between March 15, 2004 and January 12, 2009 and up to \$37,500 per day for each violation that occurred after January 12, 2009.

3. Pursuant to Mo. Rev. Stat. §§ 260.425.1, 643.151.3, and 644.076.1, assess civil penalties against Teva of up to \$10,000 per day for each violation.

4. Pursuant to Mo. Rev. Stat. §§ 260.380, 643.079, and 644.096, assess against Teva hazardous waste fees and taxes, air emission fees, and actual damages for polluting waters of the State.

5. Order the Defendants to take all steps necessary to redress or mitigate the impact of their violations.

Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

I hereby certify that on March 14, 2013, the foregoing was filed electronically with the Clerk of Court to be served by means of the Notice of Electronic Filing system upon the following:

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Dated: 3/14/13


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